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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,424	04/10/2007	Darrell Sleep	11075.204-US	1958

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NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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12/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/584,424	Applicant(s) SLEEP ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38, 40-53, 55-57, 64-66 and 69-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-20, 27-37, 49-53, 55-57, 64-66, 69-75 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 21 is/are allowed.
- 6) ☒ Claim(s) 22-26, 38, 40-48 and 76-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 4, 21-26, 38, 40-48, 76-82 are pending in the case.

Claims 1-3, 5-20, 27-37, 49-53, 55-57, 64-66, 69-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/30/09.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

The following are new rejections, some not necessitated by applicant's amendments:

Claim Objections

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim 25 recites embodiments that are not encompassed by the subject matter on which the claim indirectly depends, ie. claim 4, which recites a 2 um plasmid family.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 23, 25, 26, 38, 40-48, 76-79, 81, 82 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22, 23, are vague and indefinite in the recitation of “a chaperone encoded by the plasmid is an essential gene”. There is no recitation of “a chaperone” encoded on the plasmid in amended claim 4. Since claim 4 recites that PDI is encoded by the plasmid, it is not clear if claims 22 and 23 intend the PDI in their recitation of “a chaperone”. Since this term is broader than the specific chaperone PDI, the dependent claim would have a broader scope than the claim on which it depends, which is improper.

Claim 38 (and by dependence claims 40-48) is vague and indefinite in the recitation of “a host cell of a parent cell” since it is not clear what is intended by this phrase. Claim 38 is additionally vague and indefinite in the recitation of “the recombinant gene encoding PDI is on a plasmid **and**/or the recombinant gene encoding PDI is chromosomally integrated...” [emphasis added] since it is unclear how the gene (singular) could be both on a plasmid and be chromosomally integrated.

Claim 40, 44, 48, 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

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the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 44 and 48 recites the broad recitation "at the locus of an endogenously encoded PDI gene", and the claim also recites "preferably without disrupting the expression of the endogenous PDI gene" which is the narrower statement of the range/limitation. Claims 40 and 80 recites the broad recitation "the transferrin family" and also recites "e.g. lactoferrin" which is the narrower statement of the range/limitation. It is noted that a statement of preferences should appear in the specification, not the claims. In the claims, statements of examples and preferences lead to confusion regarding scope.

Claim 25, 26, is vague and indefinite in the recitation of "the plasmid is based on..." since it is not clear what is intended to be encompassed by this phrase. For instance, would a plasmid comprising a single nucleotide from one of the recited named plasmid constitute a plasmid "based on" said named plasmid?

Claims 38, 40-48, 76-82 are vague and indefinite in the recitation of “transferrin-based protein” since it is not clear what is intended to be encompassed by this phrase. For instance, would a protein comprising a single amino acid from transferrin be a “transferrin-based protein”?

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 81 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a host cell which comprises recombinant genes encoding a PDI and a transferrin-based protein, wherein the gene encoding the transferrin-based protein is chromosomally integrated. Since the “recombinant” genes may be identical to the native genes, the claim does not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The addition of terms such as “isolated” or “purified” would be remedial. *See* MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 40, 43, 45, 47, 81, are rejected under 35 U.S.C. 102(b) as being anticipated by Shusta et al. (Nature Biotechnol. 16, 773-777 (1998) (cited by applicants)).

It is noted preliminarily that the term “transferrin-based protein” or “a variant or fragment thereof or a fusion protein comprising transferrin, a variant or fragment thereof” encompasses virtually any protein. Shusta et al. disclose a host cell comprising a recombinant gene encoding PDI which is chromosomally integrated such that the level of PDI production is increased, and a copy of a gene encoding a transferrin-based protein or variant of transferrin, which is disclosed to be either chromosomally integrated or on a plasmid (see page 773, second col. second paragraph).

Claims 4, 21, are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
10/24/10